

REMARKS

This responds to the Office Action mailed on July 28, 2005, and the reference cited therewith.

Claims 29 and 32 are amended, no claims are canceled, and claims 33 and 34 are added; as a result, claims 11-15, 17-29, and 31-34 are now pending in this application. The amendments to the claims and the added claims are fully supported by the specification as originally filed, and no new matter has been added.

Applicants hereby respectfully request further examination and reconsideration of the application, in view of the following remarks.

§102 Rejection of the Claims

Claims 11-12, 17-18, 26, 29 and 31-32 were rejected under 35 U.S.C. § 102(e) for anticipation by Salo (U.S. Patent Publication No. 20030125774) now (U.S. Patent No. 6,892,095). Applicants respectfully traverse these rejections.

“If the examination . . . does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of [a] patent.” *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992)(emphasis added). Applicants respectfully submit that the Office Action dated July 28, 2005 has not made out a *prima facie* case of anticipation on at least the following grounds.

First, as stated by the Federal Circuit in *W. L. Gore & Associates v. Garlock, Inc.*, “anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). The Federal Circuit has indicated that “[i]n deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 U.S.P.Q. 481, 485.

To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. USA v. Monsanto Co.*, 948

F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Id.* at 1269, 20 U.S.P.Q.2d at 1749. The fact that a prior art reference is capable of being modified and the modification would anticipate the invention is not sufficient to support anticipation based on inherency.

Second, “[u]nder 35 U.S.C. §102, anticipation requires that . . . the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo N. V. v. United States Int’l Trade Comm’n*, 808 F.2d 1471, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). The Federal Circuit has added that the anticipation determination is viewed from one of ordinary skill in the art: “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). In other words, the prior art reference must put the claimed invention in the hand of one skilled in the art. *In re Donohue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). Furthermore, a term is not to be given a meaning repugnant to its usual meaning. *See In re Hill*, 161 F.2d 367, 73 U.S.P.Q. 482 (C.C.P.A. 1947). Accordingly, when the reference relied on is subject to more than one interpretation, it is the interpretation of one of ordinary skill that is to be followed.

Third, a holding of no anticipation may be found in instances where the prior art application or use is different than the applicant’s application or use. *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1183 (2001). “The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import.” M.P.E.P. § 608.01(o).

Claims 11-12, 17-18, 26, 29 and 31-32:

Applicants submit that the interpretation of Salo used by the Office Action as the underlying premise to reject claims 11-12, 17-18, 26, 29 and 31-32 is unsound. The Office Action asserts that Salo “discloses the great vein, which is a coronary vein, is equivalent to the coronary sinus.” (Office Action, p. 3). Such interpretation of Salo: (1) is not in accord with

knowledge held by one of ordinary skill in the art, and (2) cannot be read in conjunction with other portions of the reference.

Numerous objective sources recognize the fact that the coronary sinus is not the same as a coronary vein. As one example, Gray's Anatomy of the Human Body states "most of the veins of the heart open into the coronary sinus." (www.bartleby.com/107/166.html, ¶ 2). The tributaries, which are also commonly referred to as branches, of the coronary sinus are "the great, small, and middle cardiac veins, the posterior vein of the left ventricle, and the oblique vein of the left atrium, all of which, except the last, are provided with valves at their orifices." (*Id.*, ¶ 3). The University of Iowa's on-line version of Virtual Hospital affirms the coronary sinus receives the great, middle, and small cardiac veins and thus is distinct from such veins. (<http://www.vh.org/adult/provider/anatomy/AnatomicVariants/Cardiovascular/Text/Veins/CoronarySinus.html>). In fact, Virtual Hospital states "[t]he coronary sinus may be obliterated or absent . . . [in which case] [t]he great cardiac vein then drains into the superior vena cava or left brachiocephalic vein via the oblique vein of Marshall." Other exemplary sources recognizing the coronary sinus as being different from a coronary vein include Merriam-Webster's definition of a "coronary vein" found at <http://www.merriam-webster.com/cgi-bin/dictionary?book=Dictionary&va=coronary+vein> and GPnotebook's definition of "coronary sinus" found at <http://www.gpnotebook.co.uk/simplepage.cfm?ID=-200933319>.

The Federal Circuit has repeatedly held an anticipation determination must be viewed from one of ordinary skill in the art. In addition, it has been held that a term is not to be given a meaning repugnant to its usual meaning. The Office Action assertion that Salo "discloses the great vein . . . is equivalent to the coronary sinus," (Office Action, p. 3), is in contrast to knowledge of one of ordinary skill in the art and with the usual meanings of the terms "coronary vein" and "coronary sinus." In addition, such Office Action assertion cannot be read in agreement with other portions of the Salo reference. As one example, Salo recites "[t]he lead system 1 is guided through the coronary sinus 6 to a coronary vein 7 of the left ventricle 5." (Salo, [0039]).

In light of the foregoing, response to each of the Office Action claim rejections is as follows.

Claims 11-12 and 17-18:

Applicants cannot find in Salo “measuring a temperature change in the coronary sinus,” as recited in Applicants’ claim 11. The Office Action appears to recognize this; however, the Office Action asserts an average coronary sinus blood temperature discussed on page 2, paragraph 20 of Salo “can be updated by subsequent measurements as disclosed on page 2, paragraph 14, [that is,] ‘the method, adaptively modifying the delivery of synchronized electrical signals can further include comparing a measured coronary vein blood temperature with a long-term average coronary vein temperature.’” (Office Action, p. 3). As discussed above, the coronary sinus is not the same as a coronary vein. In addition, the mere fact that a certain thing may result from a given set of circumstances is not sufficient, as held in *Continental Can Co.* 948 F.2d at 1268, 20 U.S.P.Q.2d at 1749.

Claims 12-15, 17-18, and 33 are dependent on claim 11 and are patentable over Salo for the reasons argued above, in addition to the elements in such claims. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. §102 basis of rejection of claims 11-12 and 17-18 and the objection of claims 13-15.

Claim 17:

In addition to the foregoing differences, Applicants cannot find in Salo “adjusting delivery of pacing signals in light of the temperature change in the coronary sinus,” as recited in Applicants’ claim 17. As pointed out by the Office Action, Salo recites adaptively adjusting delivered electrical impulses “based on sample readings from the thermal sensor 9.” (Office Action, p. 4). Thermal sensor 9 is not located within the coronary sinus 6, and therefore does not measure the temperature within the coronary sinus as claimed by the Applicants. Rather, thermal sensor 9 measures the temperature within coronary vein 7. (*See, e.g.,* Salo, [0011], describing “[a] lead system includ[ing] . . . at least one thermal sensor at a distal end of the lead system”; Salo, [0039], stating that “[the] distal end of the lead system 1 is lodged into the coronary vein 7”; Salo, FIG. 2; Salo, [0040], stating that “lead system 1 includes at least one thermal sensor 9 at a distal tip”). As discussed above, the coronary sinus is not the same as a coronary vein.

Because Salo does not teach or suggest all of the claimed subject matter, Applicants respectfully request withdrawal of the 35 U.S.C. §102 basis of rejection of claim 17.

Claim 18:

In addition to the foregoing differences, Applicants cannot find in Salo “using the temperature change in the coronary sinus as an indicator of a change in the functional status of the heart,” as recited in Applicants’ claim 18. The Office Action implicitly acknowledges that Salo does not describe using temperature changes in the coronary sinus as an indicator of a change in the functional status of the heart; however, the Office Action asserts that “Salo discloses that an increase in activity results in an increase in [coronary vein] temperature[, and] [t]herefore, monitoring [such] temperature inherently acts as an indicator to the change in the functional status of the heart.” (Office Action, p. 4). As discussed above, the coronary sinus is not the same as a coronary vein.

Because Salo does not teach or suggest all of the claimed subject matter, Applicants respectfully request withdrawal of the 35 U.S.C. §102 basis of rejection of claim 18.

Claims 26 and 29-32:

Applicants’ claim 26 contains similar limitations as Applicants’ claim 11 and 17, including “pacing the heart with the lead, and adjusting delivery of pacing signals” using a temperature measured “in the coronary sinus,” and is patentable over Salo for similar reasons.

Claims 27-29, 31-32, and 34 are dependent on claim 26 and are patentable for the reasons argued above, in addition to the elements in such claims. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. §102 basis of rejection of claims 26, 29, 31-32 and the objection of claims 27-28.

Claim 29:

In addition to the foregoing differences, Applicants cannot find in Salo “measuring a difference between a first temperature within the coronary sinus and a second temperature in a right atrium, and pacing the heart in light of the difference,” as recited in Applicants’ amended claim 29.

Because Salo does not teach or suggest all of the claimed subject matter, Applicants respectfully request withdrawal of the 35 U.S.C. §102 basis of rejection of claim 29.

Claim 31:

Applicants' claim 31 contains similar limitations as Applicants' claim 18, including the use of "temperature changes in the coronary sinus as an indicator of a change in the functional status of the heart," and is patentable over Salo for similar reasons.

Claim 32:

In addition to the foregoing differences, Applicants cannot find in Salo "providing pacing pulses to the electrode when a decrease in temperature in the at least one thermal sensor within the coronary sinus is detected," as recited in Applicants' amended claim 32. Rather, as pointed out by the Office Action, Salo recites "measured temperature is detected from the thermal sensor 9 and then compared to the long-term average, which modifies pacing parameters." (Office Action, p. 4). Thermal sensor 9 is not located within the coronary sinus 6, and therefore does not measure a decrease in temperature within the coronary sinus as claimed by the Applicants. Rather, thermal sensor 9 measures the temperature within coronary vein 7. (*See, e.g.*, Salo, [0011], describing "[a] lead system includ[ing] . . . at least one thermal sensor at a distal end of the lead system"; Salo, [0039], stating that "[the] distal end of the lead system 1 is lodged into the coronary vein 7"; Salo, FIG. 2; Salo, [0040], stating that "lead system 1 includes at least one thermal sensor 9 at a distal tip"). As discussed above, the coronary sinus is not the same as a coronary vein.

Because Salo does not teach or suggest all of the claimed subject matter, Applicants respectfully request withdrawal of the 35 U.S.C. §102 basis of rejection of claim 32.

Claims 33 and 34:

In addition to the foregoing, Applicants cannot find in Salo "using the temperature change in the coronary sinus as an indicator of a change in the functional status of the heart includes determining whether a decrease in temperature has occurred" nor "wherein monitoring temperature changes in the coronary sinus includes monitoring a decrease in temperature and using the temperature decrease as an indicator of a change in the function status of the heart," as recited in Applicants' new claims 33 and 34, respectively. Rather, as pointed out by the Office Action, Salo "discloses that an increase in activity results in an increase in [coronary vein]

temperature [, and] [t]herefore, monitoring the temperature inherently acts as an indicator to the change in the functional status of the heart.” (Office Action, p. 4).

Allowable Subject Matter

Applicants acknowledge the allowance of claims 19-25. Applicants further acknowledge the allowability of claims 13-15 and 27-28 if rewritten to incorporate the elements of their parent claims, and reserve the right to rewrite such claims pending the outcome of the next Office communication.

Reservation of Right to Swear Behind References

Applicants reserve the right to swear behind any reference(s) which is/are cited in a rejection under 35 U.S.C. §§ 102(a), 102(e), 103/102(a), or 103/102(e). Statements distinguishing the claimed subject matter over the cited reference(s) are not to be interpreted as admissions that the reference(s) is/are prior art.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

QINGSHENG ZHU ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(612) 359-3276

Date

Oct. 27, 2005

By

Catherine I. Klima-Silberg
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27 day of October, 2005.

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